

What is claimed is:

Claims

1. A process for the determination of *H. pylori* antigen in a human fecal specimen which comprises:
  - (a) dispersing human fecal specimen in a sample diluent;
    1. contacting the fecal specimen in the diluent with a first antibody to form a complex of the antibody and the antigen;
    2. separating said specimen and said complex;
    3. exposing the complex to a second antibody and a portion of the second antibody reacting with said complex, one of said first and second antibody being selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof; and the other of the first and second antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen, one of said first and second antibody being bound to a solid carrier and the other being labeled with a detection agent; and
    4. detecting the amount of the labeled antibody in said complex and in turn determining the presence of *H. pylori* antigen in said fecal specimen.
2. The process of claim 1 wherein the first antibody is bound to a solid carrier and the second antibody is labeled with a detection agent.
3. The process of claim 1 wherein the first antibody is labeled with a detection agent and the second is bound to a solid carrier.
4. The process of claim 1 wherein the sample diluent is a protein based diluent.
5. The process of claim 1 wherein said first antibody is said genus directed monoclonal antibody and said second antibody is selected from the group consisting

of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof.

6. The process of claim 1 wherein the first antibody is labeled with a detection agent and the second is bound to a solid carrier.

7. The process of claim 1 wherein the sample diluent is a protein based diluent.

8. The process of claim 1 wherein said first antibody is said genus directed monoclonal antibody and said second antibody is selected from the group consisting of polyclonal antibodies, a plurality of monoclonal antibodies and mixtures thereof specific for *H. pylori* antigen.

9. The process of claim 4 wherein the sample diluent contains a protein selected from the group consisting of fetal bovine serum, normal goat serum, guinea pig serum, horse serum, casein, albumin, gelatin, and bovine serum albumin.

10. The process of claim 1 wherein after exposing the complex to the second antibody, the complex is washed with a buffer that reduces cross-reactivity or otherwise improves the specificity of the assay.

11. A process for the determination of *H. pylori* in a fecal specimen which comprises:

- (a) dispersing a human fecal specimen in a diluent;
- (b) contacting the fecal specimen in the diluent with a first antibody reactive with *H. pylori* antigen bound to a solid carrier and a second labeled antibody reactive with *H. pylori* to form a complex of the antibodies and the antigen, one of said first and second antibody being selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of *H. pylori* antigen specific monoclonal antibodies, and mixtures thereof and the other of the first and second

antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen;

- (c) separating said specimen and said complex;
- (d) detecting the labeled antibody in said complex formed in step (b) and in turn determining the presence of *H. pylori* antigen in said fecal specimen.

12. A process for the determination of *H. pylori* in a fecal specimen which comprises:

- (a) dispersing a human fecal specimen in a sample diluent;
- (b) contacting the fecal specimen in the diluent with a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and binds to *H. pylori* antigen bound to a solid carrier to form a complex of the antibody and the antigen;
- (c) separating said specimen and said complex;
- (d) contacting the antibody-antigen complex formed in step (b) with a primary antibody specific for *H. pylori* antigen obtained from an antibody-producing species to produce an antibody-antigen-antibody complex;
- (e) removing the primary antibody not present in the complex from step (c);
- (f) contacting the antibody-antigen-antibody complex formed in step (e) with a secondary antibody, said secondary antibody being an antibody that specifically binds the antibody-producing species antibody, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and
- (g) determining the presence of *H. pylori* antigen in said fecal specimen by detecting the complex formed in step (f).

13. A kit for the determination of *H. pylori* in a fecal specimen including a plate of wells having bound thereto a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen, a protein-based sample diluent and a plurality of labeled antibodies selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof.
14. A process for the determination of *H. pylori* in a fecal specimen which comprises:
  - (a) dispersing a human fecal specimen in a diluent;
  - (e) contacting the fecal specimen in the diluent with a first antibody reactive with *H. pylori* antigen bound to a solid carrier and a second labeled antibody reactive with *H. pylori* to form a complex of the antibodies and the antigen, one of said first and second antibody being selected from the group consisting of polyclonal antibodies for *H. pylori* antigen, a plurality of *H. pylori* antigen specific monoclonal antibodies, and mixtures thereof and the other of the first and second antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen;
  - (f) separating said specimen and said complex;
  - (g) detecting the labeled antibody in said complex formed in step (b) and in turn determining the presence of *H. pylori* antigen in said fecal specimen.
15. A process for the determination of *H. pylori* in a fecal specimen which comprises:
  - (a) dispersing a human fecal specimen in a sample diluent;
  - (h) contacting the fecal specimen in the diluent with a genus directed monoclonal antibody that reacts with different species and strains of

*Helicobacter* or *Campylobacter* and binds to *H. pylori* antigen bound to a solid carrier to form a complex of the antibody and the antigen;

- (i) separating said specimen and said complex;
- (j) contacting the antibody-antigen complex formed in step (b) with a primary antibody for *H. pylori* antigen obtained from an antibody-producing species to produce an antibody-antigen-antibody complex;
- (k) removing the primary antibody not present in the complex from step (c);
- (l) contacting the antibody-antigen-antibody complex formed in step (e) with a secondary antibody, said secondary antibody being an antibody that specifically binds the antibody-producing species antibody, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and
- (m) determining the presence of *H. pylori* antigen in said fecal specimen by detecting the complex formed in step (f).

16. A kit for the determination of *H. pylori* in a fecal specimen including a plate of wells having bound thereto a genus specific monoclonal antibody for *H. pylori* antigen, a protein-based sample diluent and a plurality of labeled antibodies for *H. pylori* antigen.